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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/029,686 | 03/03/98 | MALFROY-CAMINE | B 15390-000450 |

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EXAMINER

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| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED:

10/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/029,686

Applicant(s)

Malfroy-Camine et al

Examiner

C. Delacroix-M

Group Art Unit

1654

☒ Responsive to communication(s) filed on 9/21/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Continued Prosecution Application

1. The request filed on Sep. 21, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/029,686 is acceptable and a CPA has been established. An action on the CPA follows.

No claims are cancelled or added. Claims 1-24 are presented for prosecution on the merits.

Priority

2. If applicant desires priority under 35 U.S.C. 119 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Specification

3. The disclosure is objected to because of the following informalities: This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

4. Claims 2, 3, 5, 10, 12, 13, 22 are objected to because of the following informalities: in claim 2, line 2, "Fig. 12" should read --Fig. 12(A-B)-- and "Fig. 19" should read --Fig. 19A--. At line 3 of claim 2, "Fig. 11" should read --Fig. 11A-B--. Finally, Figs. 23 and 26A-E do not show the claimed compounds and any reference thereto should be cancelled.

Claims 3, 5, 13 and 22 need reference to the corresponding figures that disclose the claimed compounds. In claim 10, at line 3, "Fig. 11" should read --Fig. 11A--. Finally, in claim 12, line 29, "Fig. 11" does not reflect the claimed structures and any reference thereto should be cancelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1, 4, 5, 10, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 10 are vague and indefinite because at lines 16-17, lines 19-23 and lines 6-7, respectively, the phrase "selected from the group...or.." is improper Markush terminology. The metes and bounds of said phrase are unclear. Please refer to MPEP 2173.05(h) for guidance on proper Markush terminology.

Claims 4 and 12 are vague and indefinite because it is not clear to the Examiner to what the phrase "the allowed substituents" refers. Furthermore, in claim 12, at lines 24-25, it is not clear what is being claimed in the phrase "a salen metal compound having detectable antioxidant activity and according to..." . The sentence structure is awkward.

6. Claim 24 provides for the use of a salen-metal compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Malfroy-Camine et al, 5,403,834.

Malfroy-Camine discloses the invention substantially as claimed. Specifically, Malfroy-Camine teaches Applicant's claimed salen-metal compounds and pharmaceutical compositions thereof. Malfroy-Camine further disclose (1) methods for treating and preventing pathological conditions such as preventing or reducing ischemic/reperfusion damage to the myocardium and central nervous system or (2) methods for preventing or reducing cellular damage resulting from exposure to compounds which produce damaging free radicals comprising administering compositions of the disclosed salen-metal compounds. Please refer to col. 5, line 54 to col. 6, line 6; col. 16-19; col. 20-21; claims 1-6.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,827,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims of the '880 patent recite similar salen-metal compounds, pharmaceutical compositions and antioxidant compositions thereof and methods of inhibiting damage to cells induced by reactive oxygen species, wherein the substituents, i.e. X1, X2, X3, X4 and Y1-6, of the claimed salen-metal compound of the instant invention overlap with the substituents disclosed in US '880. The compounds of US '880 are encompassed and rendered obvious by the broader compounds of the instant invention.

11. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,834,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims of the '509 patent recite similar salen-metal compounds and pharmaceutical compositions thereof wherein the substituents, i.e. X1, X2, X3, X4 and Y1-6, of the claimed salen-metal compound of the instant invention overlap with the substituents disclosed in US '509. The compounds of US '509 are encompassed and rendered obvious by the broader compounds of the instant invention.

12. Claims 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,696,109. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims of the '109 patent recite similar salen-metal compounds, pharmaceutical compositions thereof and methods of arresting or treating free radical-associated diseases, wherein the substituents, i.e. X1, X2, X3, X4; Y1-6; R1-4; n; M; A of the claimed salen-metal compound of the instant invention overlap with the substituents disclosed in US '109. The more specific compounds of US '109 are encompassed and rendered obvious by the broader compounds of the instant invention.

13. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,403,834. Although the

conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims of the '834 patent recite similar salen-metal compounds and pharmaceutical compositions thereof, wherein the substituents, i.e. X1, X2, X3, X4; Y1-6; M; A; n, of the claimed salen-metal compound of the instant invention overlap with the substituents disclosed in US '834. The more specific compounds of US '834 are encompassed and rendered obvious by the broader compounds of the instant invention.

Conclusion

Hence, claims 1-24 are rejected.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward PhD, can be reached on (703) 308-4028. The fax phone number for this Group is (703) 308-4242.

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Applicant: MALFROY-CAMINE et al.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM 

Oct. 1, 1999


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600